§170.315(b)(3) Electronic prescribing

2015 Edition Cures Update CCG

Version 1.0 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	06-15-2020

Regulation Text

Regulation Text

§ 170.315(b)(3) *Electronic prescribing.*

(ii) For technology certified subsequent to June 30, 2020:

(A) Enable a user to perform the following prescription-related electronic transactions in accordance with the standard specified in § 170.205(b)(1) and, at a minimum, the version of the standard specified in § 170.207(d)(3) as follows:

(1) Create new prescriptions (NewRx).

(2) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).

(3) Request and respond to cancel prescriptions (CancelRx, CancelRxResponse).

(4) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).

(5) Receive fill status notifications (RxFill).

(6) Request and receive medication history (RxHistoryRequest, RxHistoryResponse).

(7) Relay acceptance of a transaction back to the sender (Status).

(8) Respond that there was a problem with the transaction (Error).

(9) Respond that a transaction requesting a return receipt has been received (Verify).

(B) Optionally, enable a user to perform the following prescription-related electronic transactions in accordance with the standard specified in § 170.205(b)(1) and, at a minimum, the version of the standard specified in § 170.207(d)(3) as follows:

(1) Create and respond to new prescriptions (NewRxRequest, NewRxResponseDenied).

(2) Send fill status notifications (RxFillIndicatorChange).

(3) Ask the Mailbox if there are any transactions (GetMessage).

(4) Request to send an additional supply of medication (Resupply).

(5) Communicate drug administration events (DrugAdministration).

(6) Request and respond to transfer one or more prescriptions between pharmacies (RxTransferRequest, RxTransferResponse, RxTransferConfirm).

(7) Recertify the continued administration of a medication order (Recertification).

(8) Complete Risk Evaluation and Mitigation Strategy (REMS) transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).

(9) Electronic prior authorization (ePA) transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse and PACancelRequest, and PACancelResponse).

(C) For the following prescription-related transactions, the technology must be able to receive and transmit the reason for the prescription using the diagnosis elements: <Diagnosis><Primary> or <Secondary>:

(1) Required transactions

(i) Create new prescriptions (NewRx).

(ii) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).

(iii) Request to cancel prescriptions (CancelRx).

(iv) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).

(v) Receive fill status notifications (RxFill).

(vi) Receive medication history (RxHistoryResponse).

(2) Optional transactions:

(i) Request to send an additional supply of medication (Resupply)

(ii) Request and respond to transfer one or more prescriptions between pharmacies (RxTransferRequest, RxTransferResponse)

(iii) Complete Risk Evaluation and Mitigation Strategy (REMS) transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).

(iv) Electronic prior authorization (ePA) transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse and PACancelRequest, PACancelResponse).

(D) *Optional*. For each transaction listed in paragraph (b)(3)(ii)(C) of this section, the technology must be able to receive and transmit reason for prescription using the <IndicationforUse> element in the Sig segment.

(E) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (i.e., not cc).

(F) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

Standard(s) Referenced

Paragraph (b)(3)(i)

§ 170.205(b)(1) NCPDP SCRIPT Standard, Implementation Guide, Version 2017071

§ 170.207(d)(3) RxNorm, September 8, 2015 Full Release Update

Certification Companion Guide: Electronic prescribing

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (Cures Act Final Rule). It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent, please consult the ONC Cures Act Final Rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(b)(3). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(b) "paragraph (b)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (b) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, an exception exists for § 170.315(e)(1) "VDT" and § 170.315(e)(2) "Secure Messaging" which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - End-user device encryption (§ 170.315(d)(7))
  - Integrity (§ 170.315(d)(8))
  - Encrypt authentication credentials (§ 170.315(d)(12))
  - Multi-factor authentication (§ 170.315(d)(13))
- If choosing Approach 2:

- For each applicable P&S certification criterion not certified for Approach 1, the health IT developer submits system documentation that is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces that enable the Health IT Module to access external services necessary to meet the requirements of the P&S certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- Safety-enhanced design (§ 170.315(g)(3))
- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- After January 1, 2020 testing will not be allowed for version 10.6 of the NCPDP SCRIPT standard.
- Health IT developers have until May 2, 2022 to test and certify to the updated 2015 Edition Cures Update using the SCRIPT 2017071 standard and all associated transactions.

- A transaction being “optional” for the purposes of certification does not mean and should not be interpreted as “optional” for Medicare Part D e-prescribing program compliance.
- The intended scope of this certification criterion is the ability of health IT to electronically exchange information with external recipients. [see also the FAQ #22]
- The criterion does not prohibit, nor does it require prescriptions of controlled substances to be supported to demonstrate compliance with its requirements. However, controlled substances could be used as part of testing and certification so long as the health IT has met the Drug Enforcement Agency's requirements.
- With the exception of which test data elements might be required, this certification criterion applies equally to both inpatient and ambulatory settings.
- Errors received during testing related to the max field requirement can be treated as a warning. This does not remove the requirement from a surveillance perspective nor the general need for mandatory fields to be populated with data as required by the standard. Please consult NCPDP to engage in further dialogue regarding its standard's interpretive requirements.
- It is beyond the scope of this certification criterion to require the capability to ensure that a provider is actively alerted when an electronic prescription fails. [see also 77 FR 54200] Developers are advised, but not required, to include in its disclosures whether and how failed electronic prescriptions are presented to the end-user. Developers are also advised to incorporate how failed electronic prescriptions are presented to the end-user in its end-user training materials.

Paragraph (b)(3)(ii)(A)

Technical outcome – A user can send and receive the specified prescription transactions electronically per the NCPDP SCRIPT Standard Implementation Guide Version 2017071 and using RxNorm vocabulary codes.

Clarifications:

- RxNorm is considered a minimum standard code set under the Program, and developers are permitted to upgrade their products to comply with a newer version of RxNorm without adversely affecting a product’s certification status pursuant to 45 CFR 170.555(b)(2) as long as no other law prohibits such action. [see 85 FR 25680]
- We intend for the RxNorm concept unique identifiers (RXCUIs) to be used as drug qualifiers. [see also 77 FR 54199]

- All medications may not yet have an equivalent RxNorm code. Where no RxNorm code exists, nothing prohibits another allowable code from being used. However, where corresponding RxNorm codes exist, health IT must be able to use those codes. [see also 77 FR 54199]
- Developers have flexibility in determining how message notifications are presented to users. We recommend developers and providers work together to determine whether batch-notification is preferable to real-time messaging alerts. Note that the notifications will differ based on the message type. [see also 80 FR 62642]

Paragraphs (b)(3)(ii)(B) *Optional*

Technical outcome – A user can send and receive the specified prescription transactions electronically per the NCPDP SCRIPT Standard Implementation Guide Version 2017071 and using RxNorm vocabulary codes.

Clarifications:

- The intent for the optional transaction (b)(3)(ii)(B)(2) Receive fill status notifications, specified in § 170.205(b)(1) and, at a minimum, the version of the standard specified in § 170.207(d)(3), to be RxFillIndicatorChange and not RxFillIndicator. Health IT Modules should be able to send and receive RxFillIndicatorChange transactions.

Paragraph (b)(3)(ii)(C)

Technical outcome – Technical outcome – For all transactions in provision (b)(3)(ii)(C), health IT can send and receive the reason for the prescription using the Diagnosis elements in the Medication Segment.

Clarifications:

- Health IT certified to the updated § 170.315(b)(3) criterion must have the capacity to enable a user to receive and transmit the reason for the prescription using the Diagnosis elements in the <Diagnosis><Primary> or <Secondary> elements, or optionally, the technology must be able to receive and transmit the reason for the prescription using the <IndicationForUse> element, and be consistent with the International Statistical Classification of Diseases and Related Health Problems (ICDs) sent in the diagnosis element(s). The <IndicationforUse> element defines the indication for use of the medication as meant to be conveyed to the patient, and is included in the Sig. This requirement applies to the following transactions: NewRx, RxChangeRequest, RxChangeResponse, CancelRx, RxRenewalRequest, RxRenewalResponse, RxFill, RxHistoryResponse, Resupply, RxTransferRequest,

RxTranferResponse, REMSInitiationRequest, REMSInitiationResponse, REMSRequest, REMSResponse, PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, and PACancelResponse.

Paragraph (b)(3)(ii)(D) *Optional*

Technical outcome – Optional – For all transactions in provision (b)(3)(ii)(C), health IT can send and receive the reason for the prescription using the Indication elements in the SIG segment.

Clarifications:

- Health IT certified to the updated § 170.315(b)(3) criterion must have the capacity to enable a user to receive and transmit the reason for the prescription using the Diagnosis elements in the <Diagnosis><Primary> or <Secondary> elements, or optionally, the technology must be able to receive and transmit the reason for the prescription using the <IndicationforUse> element, and be consistent with the International Statistical Classification of Diseases and Related Health Problems (ICDs) sent in the Diagnosis element(s). The <IndicationforUse> element defines the indication for use of the medication as meant to be conveyed to the patient, and is included in the Sig. This requirement applies to the following transactions: NewRx, RxChangeRequest, RxChangeResponse, CancelRx, RxRenewalRequest, RxRenewalResponse, RxFill, RxHistoryResponse, Resupply, RxTransferRequest, RxTranferResponse, REMSInitiationRequest, REMSInitiationResponse, REMSRequest, REMSResponse, PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, and PACancelResponse.

Paragraph (b)(3)(ii)(E)

Technical outcome – Oral liquid medications can only be electronically prescribed using “mL” units.

Clarifications:

- We clarify that the volume for oral liquid medications must be prescribed using “mL” units. Testing and certification do not address the concentration of active ingredients, which is the amount of active ingredient per unit of volumetric measure (e.g., 5 mg per mL). When needed, developers should represent concentrations of active ingredients using the appropriate units of measurement. E-prescribing of oral liquid medications using cc units will not be allowed for certification. [see also 80 FR 62643]

Paragraph (b)(3)(ii)(F)

Technical outcome – For all e-prescribed medications, the health IT always inserts leading zeroes before the decimal point for amounts less than one and never allows trailing zeroes after a decimal point.

Clarifications:

- No additional clarifications.

Content last reviewed on June 22, 2020